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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,828	03/22/2004	Svava Maria Atladottir	ACS-64880 (4171DX)	4223
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EXAMINER				
HOUSTON, ELIZABETH				
ART UNIT		PAPER NUMBER		
3731				
MAIL DATE		DELIVERY MODE		
10/21/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/806,828

**Applicant(s)**

ATLADOTTIR ET AL.

**Examiner**

ELIZABETH HOUSTON

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 38, 40 and 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)  
Paper No(s)/Mail Date 08/29/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/11/08 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-10, 15, 38, 40, 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Duffy et al (US 6,086,611).**

4. Duffy discloses a self-expanding stent (Fig. 3) for treating a bifurcated vessel. The stent has a plurality of rings (7 and 11) aligned along a common axis, adjacent rings being connected by links (6). The stent has a proximal section, distal section and central section (see below) each such section being defined by selected rings of said plurality of rings. The number of first peaks (indicated by circles in figure below) in each of the rings of the central section differs from the number of first peaks in the rings of the

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distal and proximal sections thereby providing additional material for apposing a side branch vessel. The first peaks of the rings of the central section are configured to (capable of) flare outward radially into an opening to the side branch vessel (see Figs. 6A-6C). The proximal section has 7 first peaks. (The proximal section shows 4 peaks. It is inherent that there are at least three on the side not shown.) The distal section has 6 first peaks. (The distal section shows 3 peaks. It is inherent that there are at least three on the side not shown.) The central section has 8 peaks. (The central section shows 6 peaks. It is inherent that there are at least two on the side not shown.) The number of first peaks in the rings of the central section is greater than the number of first peaks in any of the rings of the proximal or distal sections. The distal opening and the proximal opening are aligned along the stent longitudinal axis (depending on what type of bifurcated vessel the stent is delivered to and when the stent is the delivery configuration (fig. 4)). The central opening is offset radially from the proximal and distal openings.

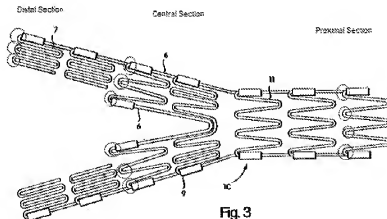
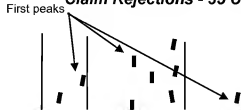


Fig. 3

**Claim Rejections - 35 USC § 103**



5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**6. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al (US6,086,611) in view of Guruwaiya (US 6,251,136).**

7. Duffy discloses the invention substantially as claimed except for the layer of drug and the primer material. Guruwaiya discloses a stent coated with a primer layer, which readily adheres to the material of the stent and is in turn constructed to retain a layer of pharmacological agent (Col 2: L20-34). Guruwaiya discloses that it is well known to be beneficial to deliver drugs with stents to treat problems such as thrombosis or neointimal hyperplasia. Guruwaiya further discloses using a primer layer of a polymer that more readily carries and releases the drugs as a benefit to layering the drug directly to the stent material.

8. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a drug layer into the bifurcated stent since it is an old and well known enhancement to be able to treat the tissue with drugs while at the same time providing the treatment of the stent. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a primer layer between the stent layer and the drug layer since the primer layer will more readily carry and release the drug that the stent material may not be able to carry and release.

**9. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy et al. (US 6,086,611)**

10. As to claim 42, Duffy teaches a bifurcated stent substantially as claimed but does not disclose that the stent is formed from a single hypotube. The claimed phrase "formed from a single hypotube" is being treated as a Product by Process limitation. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

11. Thus, even though, Duffy forms the stent by a different process, it appears that the product disclosed by Duffy would be the same or similar as that claimed; especially since both applicant's product and the prior art product are a bifurcated stent with a middle section that flares into the branch vessel.

***Response to Arguments***

12. Applicant's arguments with respect to claim 1-15, 38, 40-42 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./  
Examiner, Art Unit 3731

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731